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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PHILIP CONNOLY

Appeal 2008-4110
Application 10/045,803
Technology Center 1700

Decided: November 20, 2008

Before ERIC GRIMES, LORA M. GREEN, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 1-3, 7, 8, and 10. Jurisdiction is under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The claims are drawn to the oral administration of milk protein concentrate and probiotic bacteria to a subject. Claims 1-3, 7, 8, and 10 are pending and stand rejected by the Examiner as follows:

- 1) Claims 1-3, 7, 8, and 10 under 35 U.S.C. § 103(a) as obvious over Meister et al. (US 6,200,609 B1, Mar. 13, 2001) (Ans. 3);
- 2) Claims 1, 2, 7, and 10 under 35 U.S.C. § 103(a) as obvious over Bohren (US 3,793,465, Feb. 19, 1974) (Ans. 4);
- 3) Claim 1 under 35 U.S.C. § 103(a) as obvious over Kronberg (US 2,127,524, Aug. 23, 1938), Jameson (US 5,356,640, Oct. 18, 1994), Nielsen (US 5,232,720, Aug. 3, 1993), or Kosikowski (US 5,098,721, Mar. 24, 1992) (Ans. 4); and
- 4) Claims 1-3, 7, 8, and 10 under 35 U.S.C. § 112, second paragraph, as indefinite (Ans. 3).

Claims 1, 7, and 10 are representative of the appealed subject matter and read as follows:

1. A method of promoting protein absorption and utilization from the gastrointestinal tract of a subject comprising the oral administration of a combination of milk protein concentrates and probiotic bacteria in an amount sufficient to increase the subject's total daily consumption of protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day; the milk protein concentrate having a protein content of about 65% to about 90% and there being about 100,000 to about 50,000,000 probiotic bacteria organisms per gram of milk protein concentrate.

7. A method of promoting protein utilization and absorption in a subject on a high protein diet comprising the oral administration of combination of milk protein concentrates and

probiotic bacteria, the probiotic bacteria being selected from the group consisting of *bifido* bacteria, *Lactobacillus plantarum*, *Lactobacillus helveticus*, *Lactobacillus paracasei*, *Lactobacillus bulgaricus*, *Streptococcus thermophilus* and combinations thereof; the subject being administered an amount of the combination sufficient to increase the subject's total daily consumption of protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day.

10. A method of promoting higher ratio of anabolism as compared to catabolism, promoting muscle tissue growth, promoting amino acid production in the intestinal tract in an athlete and promoting the utilization of protein consumed by the athlete, the method comprising the consumption by the athlete of a combination of milk protein concentrates and probiotic bacteria, the probiotic bacteria being selected from the group consisting of *bifido* bacteria, *Lactobacillus plantarum*, *Lactobacillus helveticus*, *Lactobacillus paracasei*, *Lactobacillus bulgaricus*, *Streptococcus thermophilus* and combinations thereof; the athlete consuming an amount of the combination sufficient to increase the athlete's total daily consumption of protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day.

ISSUE ON APPEAL

Independent claims 1, 7, and 10 are each directed to administration of probiotic bacteria and a milk protein concentrate in an amount "sufficient to increase the . . . total daily consumption of protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day." Claim 1 further requires administration of a specific amount of bacteria: "about 100,000 to about 50,000,000 probiotic bacteria organisms per gram of milk protein concentrate.

The Examiner relies on the cited prior art references for their teachings of edible probiotic bacteria and milk protein. The Examiner acknowledges that the prior art does not disclose the claimed amounts of milk protein and bacteria, but contends that such amounts would be arrived at by routine experimentation aimed at determining the optimal amount of milk protein to be consumed by a subject (Ans. 4).

The issue in this appeal is as follows:

Does the prior art suggest the claimed amounts of milk protein concentrate recited in claims 1, 7, and 10, and probiotic bacteria in claim 1?

OBVIOUSNESS OVER MEISTER

Claims 1-3, 7, 8, and 10 stand rejected under 35 U.S.C. § 103(a) as obvious over Meister.

Findings of Fact (FF)

Scope and content of the prior art

1. Meister describes a food composition containing probiotic lactic acid bacteria, such as *Lactobacillus helveticus*, *Lactobacillus plantarum*, and bifidobacteria (Meister, at col. 2, l. 55 to col. 3, l. 5).
2. The probiotic bacteria “exclude pathogenic bacteria on human intestinal cells” and “act on the human immune system by allowing it [to] react more strongly to external aggression (immunomodulatory capacity)” (Meister, at col. 3, ll. 8-11).
3. The bacteria are added to food compositions, such as milk or a protein fraction or a hydrolysate of milk (Meister, at col. 4, ll. 25-28).
4. The compositions are prepared by spray drying the milk and probiotic bacteria conjointly (Meister, at col. 6, ll. 43-51; at col. 2, ll. 10-37).

5. Meister describes milk compositions which can comprise from 5,300,000 (5.3×10^6) to 82,000,000 (8.2×10^7) bacteria (“cfu”) per gram of food material after spray-drying (Meister, at col. 7, Table 1, “Cfu/g after spraying”). *See also*, at col. 5, l. 45, describing food powders comprising from 1 to 1,000,000,000 bacteria (10^9) per gram.

6. The Specification teaches that athletes increase their intake of protein to gain muscle tissue or mass (Spec. 2: 2-10, 27-29). Milk protein is example of a protein which is consumed to increase muscle mass (*id.* at 3: 15-19). Thus, milk protein quantity would have been recognized by persons of ordinary skill in the art as results-effective variable to boost muscle tissue mass.

Differences between the prior art and the claimed invention

7. Meister teaches a food composition comprising milk and probiotic bacteria for oral administration (FF1, 4, 5) as in claims 1, 7, and 10.

8. Meister does not describe the specific amounts of milk protein administered in claims 1, 7, and 10.

9. However, Meister describes amounts of bacteria in its food powders which overlap or which encompass the claimed range of “about 100,000 to about 50,000,000 probiotic bacteria per gram of milk protein concentrate” recited in claim 1, i.e., from 5,300,000 to 82,000,000 per gram and from 1 to 1,000,000,000 bacteria per gram, respectively (FF5).

Reason to modify the prior art

10. Persons of ordinary skill in the art would have had reason to routinely modify the amounts of milk protein and probiotic bacteria disclosed in Meister to find the “optimum total daily consumption of” protein and probiotic bacteria “needed by an individual” (Ans. 4).

Analysis

The difference between Meister and the claimed invention is that Meister does not disclose the claimed amounts of milk protein (claims 1, 7, and 10), milk protein content (claim 1), and probiotic bacteria (claim 1) (FF7). However, the Examiner finds, and we agree, that the claimed amounts would have been routinely arrived at motivated by the desire to find the optimal amounts of protein and probiotic bacteria to be consumed by a subject (FF10).

With regard to the claimed amount of milk protein, the Specification teaches that, in order to gain muscle mass, athletes increase their intake of proteins, such as protein from milk (FF6). In other words, milk protein quantity was recognized as a results-effective variable for boosting muscle mass (*id.*). An athlete would therefore have had reason to increase dietary intake of milk protein, as required by the claims, to achieve a desired gain in muscle mass.

While the claimed value of “between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day” is not disclosed by Meister, the “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” *In re Boesch*, 617 F.2d 272, 276 (CCPA 1980). As we agree that such circumstances are applicable here, we conclude that there the prior art reasonably suggests the claimed limitation of increasing “total daily consumption of protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day” as in claims 1, 7, and 10.

Claim 1 also requires an amount of “about 100,000 to about 50,000,000 probiotic bacteria organisms per gram of milk protein concentrate.” As the claimed concentration either overlaps or is encompassed by the values for the same bacteria in Meister’s food powder (FF5, 9), there is a presumption of obviousness. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003); *Iron Grip Barbell Co. v. USA Sports*, 392 F.3d 1317, 1322 (Fed. Cir. 2004).

Appellant argues that claims 1, 7, and 10 “clearly describe combining protein and probiotic bacteria prior to drying or mixing” in contrast to Meister (App. Br. 14). This argument is not persuasive. The claims are not limited to a method of preparation. Meister teaches, as do the claims, a combination of milk protein and probiotic bacteria (FF3).

Similarly, we are not persuaded by Appellant’s discussion of Meister’s process and statement that Meister is not “the Applicant’s invention” (App. Br. 14-15) because these arguments do not distinguish Meister over the limitations which are actually recited in the instant claims.

Appellant contends that Meister does not suggest increasing total daily consumption to “between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day” as recited in the claims (*id.* at 15). We disagree. The knowledge that milk protein quantity is a result-effective value for increasing muscle mass (FF6) would have provided adequate motivation to have modified the milk protein amounts in Meister to achieve the “optimum total daily consumption of” protein “needed by an individual” (Ans. 4), i.e., a desired gain in muscle mass.

For the foregoing reasons, we affirm the rejection of claims 1, 7, and 10 as obvious over Meister. Claims 2, 3, and 8 fall with claim 1 because

separate arguments for their patentability were not provided. 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS OVER BOHREN

Claims 1, 2, 7, and 10 stand rejected under 35 U.S.C. § 103(a) as obvious over Bohren.

Findings of Fact

Scope and content of the prior art

11. Bohren describes an edible milk powder to which *Lactobacillus bulgaricus* and *Streptococcus thermophilus* are added in order to acidify it (Bohren, at col. 1, ll. 25-32; at col. 3, l. 73 to col. 4, l. 5). The composition has varying amounts of milk fat and nonfat solids (protein) (*id.* at cols 3-4 (Examples 1-4)).

Differences between the prior art and the claimed invention

12. As in independent claims 1, 7, and 10, Bohren teaches an edible food composition comprising milk and probiotic bacteria, i.e., *Lactobacillus bulgaricus* and *Streptococcus thermophilus* (FF11).

13. However, Bohren does not describe the specific amount of milk protein recited in claims 1, 7, and 10 nor the specific content of probiotic bacteria in claim 1.

Reason to modify the prior art

14. Persons of ordinary skill in the art would have had reason to routinely modify the amounts of milk protein and probiotic bacteria disclosed in Bohren to find the “optimum total daily consumption of” protein and probiotic bacteria “needed by an individual” (Ans. 4).

Analysis

Claims 7 and 10

The difference between Bohren and the claimed invention is that Bohren does not disclose the claimed amounts of milk protein (claims 7 and 10) (FF12-13). However, the Examiner finds, and we agree, that the claimed amounts would have been arrived at routinely (FF14), motivated by the desire to find the optimal amounts of protein to be consumed by a subject (FF14).

As discussed above for Meister, the Specification teaches that, in order to gain muscle mass, athletes increase their intake of proteins, such as protein from milk (FF6). In other words, milk protein quantity was recognized as a results-effective variable for boosting muscle mass (*id.*). An athlete would therefore have had reason to increase dietary intake of milk protein, as required by the claim 7 and 10, to achieve a gain in muscle mass. While the claimed value of “between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day” is not disclosed by Bohren, the “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” *In re Boesch*, 617 F.2d at 276. As we agree that such circumstances are applicable here, we conclude that there the prior art reasonably suggests the claimed limitation of increasing “total daily consumption of protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day” as in claims 7 and 10.

Appellant also contends that the “[t]wo part protein concentrates appear in the Bohren patent as a two part acidic milk powder having an acid compound coated in an edible fat with an emulsifier” which “is distinct from

the two parts combined in a concentrate independent of their acidity or coating characteristics as in the present invention” (App. Br. 10).

We are not convinced by this argument that the Examiner erred. The claims use the open ended term “comprising” which does not exclude the addition of other ingredients or characteristics. Thus, while Bohren may describe its compositions as having certain coatings and acid content, there is no language which would exclude these from being present in the instant claims.

It is also argued by Appellant that “the Bohren patent does not appear to define or suggest the usage of its acidified milk product in a powder form for promoting protein absorption and utilization from the gastro intestinal track [sic] of an athlete, in the amounts as specified in these claims” (App. Br. 10-11).

Appellant is apparently referring to the preambles of claims 7 and 10 that include, *inter alia*, promoting protein utilization and other effects associated with the administration and consumption of the claimed milk protein and probiotic bacteria. Preamble language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim. *See Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003); *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997). If the body of the claim “sets out the complete invention” and the preamble does not recite essential structure that is important to the invention or necessary to give meaning to the claim, the preamble is not ordinarily treated as limiting the scope of the claim. *Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1310 (Fed. Cir. 2002);

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NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1305-06 (Fed. Cir. 2005).

In this case, the body of the claims defines administration or consumption of the claimed milk protein/probiotic combination as the necessary step to achieve the claimed effect of promoting protein absorption, etc., as recited in the claim preambles. In other words, administering the milk protein and bacteria would achieve the results recited in the claim preamble. Appellant has not identified any steps imposed by the claim preamble which are not already recited in the claim body and which are missing from the prior art. Thus, we do not regard the claim preamble as limiting the claim scope. Recognizing a result of an old process – i.e., administering milk protein and probiotic bacteria – does not make the process once again patentable.

As far as the subject to whom the composition is administered, we acknowledge that claim 10 refers to an athlete, but as that term is not defined in the Specification, we interpret it broadly to include any person who performs any type of physical exercise or exertion, and therefore it is insufficient to distinguish over the general population to which Bohren is directed.

For the foregoing reasons, we affirm the rejections of claims 7 and 10 as obvious over Bohren.

Claim 1

With respect to claim 1, we agree with Appellant (App. Br. 10) that no evidence has been provided by the Examiner of any specific amount of bacteria which is present in Bohren's food product. Consequently, the

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Examiner has not met the burden of establishing prima facie obviousness of claim 1. Accordingly, we are compelled to reverse the rejection of claim 1 and dependent claim 2.

OBVIOUSNESS OVER KRONBERG, JAMESON, NIELSEN, OR
KOSIKOWSKI

Claim 1 stands rejected under 35 U.S.C. § 103(a) as obvious over Kronberg, Jameson, Nielsen, or Kosikowski.

Analysis

Claim 1 is directed to a method involving the oral administration of a milk protein concentrate and probiotic bacteria in which there is “about 100,000 to about 50,000,000 probiotic bacteria organisms per gram of milk protein concentrate.” The Examiner has not cited evidence of the bacterial concentrations present in the food products described in the cited references. The Examiner has also not provided a reason as to why persons of ordinary skill in the art would have formulated compositions for use in the claimed method with the specifically recited probiotic bacterial concentrations.

While no explicit suggestion in the prior art is necessary to establish prima facie obviousness, the Examiner still has a burden of explaining why a person of ordinary skill in the art would have been prompted to modify the prior art to make the claimed invention, i.e., administration of “about 100,000 to about 50,000,000 probiotic bacteria organisms per gram of milk protein concentrate.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

Accordingly, we reverse the rejection of claim 1.

INDEFINITENESS REJECTION

Claims 1-3, 7, 8, and 10 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite. The Examiner contends that the claims are indefinite because they do not recite the actual amount of protein content which is administered (Ans. 3).

While the claims do not specify how much milk protein is consumed by a subject, they state that the amount administered is sufficient to increase the consumption to about 1.5 to about 4.0 grams per kilogram of body weight per day. Using the body weight of a subject and his starting daily protein intake, it could be accurately determined how much protein to administer to achieve the claimed increase in consumption. Thus, we do not agree with the Examiner that the claims are indefinite. We reverse the rejection.

CONCLUSIONS OF LAW

As Meister suggests the claimed amount of milk protein concentrate and probiotic bacteria required by claims 1-3, 7, 8, and 10, the rejection under 35 U.S.C. § 103(a) of claims 1-3, 7, 8, and 10 is affirmed.

Bohren suggests the claimed amount of milk protein concentrate recited in claims 7 and 10. Therefore, the rejection of these claims under 35 U.S.C. § 103(a) is affirmed.

The Examiner did not meet the burden of establishing that any of Bohren, Kronberg, Jameson, Nielsen, or Kosikowski suggest the specific concentration of probiotic bacteria recited in claim 1. The rejection of claims 1 and 2 over Bohren, and claim 1 over each of Kronberg, Jameson, Nielsen, or Kosikowski, is therefore reversed.

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The rejection over claim 1-3, 7, 8, and 10 under § 112, second paragraph, is reversed as these claims are not indefinite.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

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